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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/704,554	11/03/2000	Lawrence Friedhoff	0200-0004	4555

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EXAMINER	
JIANG, SHAOJIA A	
ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 08/13/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/704,554	Applicant(s) FRIEDHOFF ET AL.	
	Examiner Shaojia A Jiang	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 May 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *84-103* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *84-103* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

This Office Action is a response to Applicant's amendment and response filed on May 21, 2003 in Paper No. 18 wherein claims 1-83 have been cancelled and claims 84-103 are newly submitted. Currently, claims 84-103 are pending in this application.

Claims 84-103 are examined on the merits herein.

Applicant's amendment (canceling claims 60-83) filed on May 21, 2003 in Paper No. 18 with respect to the rejection of claims 60-83 made under 35 U.S.C. 102(b) as being anticipated by Scolnick (WO 95/06470) for reasons of record stated in the Office Action dated November 19, 2002 has been considered and is found persuasive to remove this particular rejection since claims 60-83 are cancelled. Therefore, the said rejection is withdrawn.

The following is new rejections necessitated by Applicant's amendment filed on May 21, 2003 in Paper No. 18, wherein all original claims are cancelled.

Claim Objection

Claims 84-93 and 102 are objected as to the expression "APP" in the claims herein since the expression "APP" is used to identify/describe particular process herein and, accordingly, the identification/description is unclear.

In order to expedite prosecution, claims 184-93 and 102 will be examined using the "amyloid precursor protein" as defined on page 1 of the specification as has apparently been intended.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 84-103 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The terms "suitable" in claim 84, 94, and 102-103 and "positive" in claim 98 are relative terms which renders claims 84-103 indefinite. The expression " suitable " is not clearly defined in the specification. Hence, one of ordinary skill in the art could not interpret the metes and bounds as to the recitation "a rate suitable to .." and "a positive response" in the claim. The scope of the claims is indefinite as to as to the methods encompassed thereby.

The recitations, "an osmotic agent", and "a optional first coating and a second coating" in claims 91 and 101 render claim 91-93 and 101 indefinite. The recitations, "an osmotic agent", and "a optional first coating and a second coating" are not defined in the specification. Hence, one of ordinary skill in the art could not interpret the metes and bounds as to "an osmotic agent", and "a optional first coating and a second coating". Therefore, the scope of claim is indefinite as to the methods encompassed thereby.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 84-90, 92-93 and 103 are rejected under 35 U.S.C. 102(b) as being anticipated by Scolnick (WO 95/06470).

Scolnick discloses methods of treating Alzheimer's disease or the onset of Alzheimer's disease in a human patient comprising administering to the said patient the instant therapeutically effective amount of a composition comprising an HMG-CoA reductase inhibitor (see page 11 line 14-15), in particular, lovastatin (20 mg per day, see Example 1 at page 11), simvastatin, pravastatin, and fluvastatin. Scolnick also discloses that the HMG-CoA reductase inhibitor is administered orally by a time-controlled release dosage form including osmotic devices, diffusion controlled systems, dissolution controlled matrices and erodible/degradable matrics (see particularly page 11 lines 8-11 and claim 22). Note that the therapeutically effective amount of the HMG-CoA reductase inhibitor to be administered per day in the instant invention has been disclosed in Scolnick (see page 11 line 14-15 and Example at page 11). See also abstract, page 2 lines 16-20, page 10, and claims 1-25. Scolnick further discloses that the treatment therein with the lovastatin composition underwent four consecutive nine-week periods, within the instant claimed period (see Example 1 at page 11).

Therefore, Scolnick's method inherently treats or reduces beta amyloid levels in a human which exhibits symptoms of Alzheimer's disease and Down's syndrome (both known as amyloid precursor protein processing disorders), as claimed herein since Scolnick's method steps are same as the instant method steps. See *Ex parte Novitski*,

26 USPQ 2d 1389. See also *Eli Lilly and Co. v. Barr Laboratories Inc.* 251 F3d. 955; 58 USPQ2d 1869-1881 (Fed. Cir. 2001) with regard to inherency as it related to the claimed invention herein. Moreover, Scolnick's method inherently decreases in mean beta amyloid concentration in the blood of said human patient by at least about 18 pg/ml after 1 month of treatment since decreasing in mean beta amyloid concentration in the blood of said human patient by at least about 18 pg/ml after 1 month of treatment is considered to be an inherent property of the administration of a HMG-CoA reductase inhibitor composition for the treatment herein. It is well settled that recitation of an inherent property of a composition will not further limit claims drawn to a composition.

Thus, Scolnick clearly anticipates claims 84-90, 92-93 and 103.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 91 and 94-102 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scolnick (WO 95/06470) in view of Chen et al. (5,916,59, PTO-892) and McKhann et al. (PTO-892).

The same disclosure of Scolnick has been discussed above (see supra at page 4-5).

Scolnick does not expressly the employment of the controlled release formulation of HMG-CoA reductase inhibitor comprising an osmotic agent and coating agents with a pH sensitive water insoluble polymer and further comprising an alkyl ester of a substituted naphthalene. Scolnick does not also expressly the methods therein further comprising a step for determining whether a human exhibits at lease one symptom of Alzheimer's disease.

Chen et al. discloses that the controlled release formulation of HMG-CoA reductase inhibitor, lovastatin in particular, comprising an alkyl ester of a substituted naphthalene, and an osmotic agent and coating agents with a pH sensitive water insoluble polymer (see abstract, Example 1-3 at col.6-8, and claims 1-12) is a better controlled release system and has advantages, e.g., substantially and completely delivering a HMG-CoA reductase inhibitor, lovastatin in particular without the need to provide a passageway, and additionally providing higher bioavailability (see col.2 lines 5-14).

McKhann et al. teaches that a method for determining whether a human exhibits at lease one symptom of Alzheimer's disease Alzheimer's disease is well known in the art (see the entire article of McKhann et al. and as Applicant admitted at page 11 lines 16-23 of the specification herein).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ the controlled release formulation of HMG-CoA reductase inhibitor, disclosed in Chen at el., comprising an alkyl ester of a substituted naphthalene, and an osmotic agent and coating agents with a pH sensitive water

insoluble polymer, and to employ the method for determining whether a human exhibits at lease one symptom of Alzheimer's disease taught in McKhann et al. in the instant claimed methods.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ the controlled release formulation of HMG-CoA reductase inhibitor, disclosed in Chen at el., comprising an alkyl ester of a substituted naphthalene, and an osmotic agent and coating agents with a pH sensitive water insoluble polymer, in the instant claimed methods, because the controlled release formulation of Chen at el. is known to be a better controlled release system and have advantages, e.g., substantially and completely delivering a HMG-CoA reductase inhibitor, lovastatin in particular without the need to provide a passageway, and additionally providing higher bioavailability.

Moreover, one having ordinary skill in the art at the time the invention was made would have been motivated to employ a method step for determining whether a human exhibits at lease one symptom of Alzheimer's disease in the instant claimed methods since a method for determining whether a human exhibits at lease one symptom of Alzheimer's disease is well known in the art, i.e., taught in McKhann et al. Thus, it is well within the skill of artisan to determine whether a human exhibits at lease one symptom of Alzheimer's disease using the known method and then treat the patient.

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

Applicant's remarks filed on filed on May 21, 2003 in Paper No. 18 with respect to the rejection of claims 60-83 made under 35 U.S.C. 103(a) of record in the previous Office Action November 19, 2002 have been fully considered but are moot in view of the new ground(s) of rejection above and also because claims 60-83 are cancelled by Applicants.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

S. Anna Jiang, Ph.D.
Patent Examiner, AU 1617
July 29, 2003

SREENI PADMANABHAN
PRIMARY EXAMINER